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(54) High melt flow polypropylene medical film.

(57) An impact resistant film suitable for making medical solution pouches generally includes an interior layer of a polyolefin such as an ethylene vinyl acetate copolymer, ethylene methyl acrylate copolymer, very low density polyethylene or blends thereof; and outer layers of a high melt flow propylene homopolymer or copolymer. At least one of the outer layers also includes an elastomer such as a styrene ethylene butylene styrene copolymer. A flexible copolyester can be substituted for one of the outer high melt flow polymer layers. Additional interior layers can also be incorporated in the film structure.

**EP 0 468 768 A1**

This invention relates to autoclavable flexible films suitable for the packaging of medical solutions.

Currently, it is common medical practice to supply liquids such as medical solutions for parenteral administration in the form of disposable, flexible pouches. These pouches should be characterized by collapsibility, transparency, and adequate mechanical strength. They must also be able to resist the relatively high temperatures required for heat sterilization of their contents, for example in an autoclave. Typically, medical solutions and the like are autoclaved at about 253°F for periods of 15 to 30 minutes.

Presently, such flexible pouches are typically made from a highly plasticized polyvinyl chloride. While meeting the requirements mentioned above, polyvinyl chloride may have some undesirable properties for use as a medical solution pouch because of the possibility of migration of plasticizer from the polyvinyl chloride into the medical solution or the other contents of the pouch so that the solution may become contaminated by potentially toxic material. A question has also arisen concerning whether PVC is adequately chemically neutral to medical solutions. It has also been found that polyvinyl chloride becomes brittle at relatively low temperatures.

Embrittlement and stress-cracking, particularly of the outer surface of medical pouches, has been found to occur in other non-PVC pouches. It is desirable to provide a pouch for the packaging of medical solutions which substantially reduces or eliminates stress-cracking and embrittlement of the pouch material.

Of interest is U.S. patent 4,401,536 issued to Lundell et al which discloses the use of a blend of medical grade radiation-stabilized polypropylene and a copolymer of ethylene and a comonomer selected from the group consisting of vinyl esters of saturated carboxylic acids and alkyl esters of alpha, beta ethylenically unsaturated carboxylic acids, the blend being irradiated.

Also of interest is U.S. patent 4,643,926 issued to Mueller which discloses a flexible film for medical solution pouches generally including a sealant layer of ethylene propylene copolymer, modified ethylene propylene copolymer, or flexible copolyester; one or more interior layers including elastomeric polymeric materials such as very low density polyethylene; and an outer layer of ethylene propylene copolymer or a flexible copolyester.

Of interest is EP 228 819 (Raniere et al) disclosing a multiple layer film suitable for packaging solutions used for medical services, having three layers including a sealant layer having polypropylene polymer blended with an elastomeric styrene ethylene butylene styrene copolymer.

It is an object of the present invention to provide a film suitable for the packaging of medical solutions, the film capable of production without the need for sacrificial layers.

It is an object of the present invention to provide a film suitable for the packaging of medical solutions, the film having good impact resistance and flexibility.

Another object of the present invention is to provide a film suitable for the packaging of medical solutions characterized by good optical properties and a low degree of initial haze (blushing) after autoclaving of the package.

Still another object of the present invention is to provide a film suitable for the packaging of medical solutions characterized by high mechanical strength.

The term "high melt flow" is used herein to indicate a melt flow of greater than about 5 grams/10 minutes and less than about 15 grams/10 minutes (ASTM D 1238, Condition L). Melt flow is generally considered to be inversely proportional to melt viscosity and molecular weight.

The terms "flexible" and the like and "elastomeric" and the like are used herein to define specific polymeric materials as well as characteristics of a resulting pouch or bag whereby improved flexibility and/or collapsibility of the pouch or bag is obtained by the use of these specific polymeric materials. Flexible materials may be characterized by a modulus of preferably less than 50,000 PSI (ASTM D-882-81) and more preferably less than 40,000 PSI (ASTM D-882-81).

The term "film" and the like refers to a thermoplastic material suitable for packaging and having one or more layers of polymeric materials which may be bonded by any suitable means well known in the art.

The term "polymer", "polymeric", and the like, unless specifically defined or otherwise limited, generally includes homopolymers, copolymers and terpolymers and blends and modifications thereof.

The term "interior" and the like is used herein to refer to a layer of a multilayer film which is not a skin or surface layer, or sealant layer, of the film.

The term "melt index" is used herein as the amount, in grams, of a thermoplastic resin which can be forced through a given orifice under a specified pressure and temperature within 10 minutes. The value should be determined in accordance with ASTM D 1238-82, Condition E.

The term "ethylene vinyl acetate copolymer" (EVA) is used herein to refer to a copolymer formed from ethylene and vinyl acetate monomers wherein the ethylene derived units in the copolymer are present in major amounts and the vinyl acetate derived units in the copolymer are present in minor amounts.

The term "ethylene propylene copolymer" (EPC) is used herein to refer to a copolymer formed of propylene monomer and minor amounts, usually less than 10% and preferably less than 6% by weight, of ethylene comonomer. This may be a high melt flow EPC, although it does not have to be unless designated as such in this

specification or the claims attached hereto.

The term "copolyester" and the like is applied to polyesters synthesized from more than one diol and a dibasic acid. Copolyesters as used herein may also be characterized as copolymers of polyether and polyethylene terephthalate. More preferably copolyesters as used herein may be characterized as polymeric materials derived from 1,4 cyclohexane dimethanol, 1,4 cyclohexane dicarboxylic acid, and polytetramethylene glycol ether, or equivalents of any of the above, as reactants.

The term "modified" and the like is used herein to refer to a polymeric material in which some or all of the substituents are replaced by other materials, providing a change in properties such as improved impact resistance, flexibility or elastomeric properties. In the case of modified ethylene propylene copolymer, the modification is provided by a rubbery block copolymer such as commercially available under the trademark Kraton from the Shell Chemical Company.

The terms "elastomer" and the like are used herein to mean a elastomeric, rubbery or flexible material suitable for use in one or more layers of the present invention. Preferred elastomers are styrene ethylene butylene styrene copolymer (SEBS), styrene butadiene styrene copolymer (SBS), styrene isoprene styrene copolymer (SIS), and ethylene propylene rubber (EPR).

The term "polyolefin" is used herein to refer to olefin polymers and copolymers, especially ethylene polymers and copolymers, and to polymeric materials having at least one olefinic comonomer, such as ethylene vinyl acetate copolymer.

An impact resistant film in accordance with the invention comprises two outer layers each comprising a high melt flow ethylene propylene copolymer; and an interior layer disposed between the two outer layers, and comprising an ethylene vinyl acetate copolymer (EVA), ethylene methyl acrylate copolymer (EMA), or blends thereof; at least one of the outer layers also including an elastomer.

Alternatively, an impact resistant film comprises a first outer layer comprising a blend of a high melt flow ethylene propylene copolymer and an elastomer; a second outer layer comprising a copolyester; and a polymeric adhesive layer disposed between and adhering the first and second outer layers.

In another aspect of the invention, an impact resistant film comprises a first outer layer comprising a blend of a high melt flow ethylene propylene copolymer and an elastomer; a second outer layer comprising a copolyester; an interior layer comprising an ethylene vinyl acetate copolymer, ethylene methyl acrylate copolymer, or a blend thereof; and a polymeric adhesive layer disposed between and adhering the interior layer to the second outer layer.

In yet another aspect of the invention, an impact resistant film comprises a first outer layer comprising a blend of a high melt flow ethylene propylene copolymer and an elastomer; a second outer layer comprising a copolyester; a central layer comprising a polyolefin; and polymeric adhesive layers disposed between and adhering the respective outer layers to the central layer.

Alternatively, an impact resistant film comprises two outer layers each comprising a high melt flow ethylene propylene copolymer; a central layer comprising a fractional melt index ethylene vinyl acetate copolymer; an interior layer disposed between each of the two outer layers and the central layer respectively and comprising ethylene vinyl acetate copolymer having a melt index greater than about 1; and at least one of the outer layers also including an elastomer.

A modification of the above is an impact resistant film comprising two outer layers each comprising a high melt flow ethylene propylene copolymer; a central layer comprising ethylene vinyl acetate copolymer having a melt index greater than about 1; an interior layer disposed between each of the two outer layers and the central layer respectively and comprising a fractional melt index ethylene vinyl acetate copolymer; and at least one of the outer layers also including an elastomer.

In still another aspect of the invention, an impact resistant film comprises a first outer layer comprising a blend of a high melt flow ethylene propylene copolymer and an elastomer; a second outer layer comprising a copolyester; a central layer comprising a polyolefin; an interior layer disposed between the first outer layer and the central layer, and comprising ethylene vinyl acetate copolymer having a melt index greater than about 1; and a polymeric adhesive layer disposed between and adhering the copolyester layer to the central layer.

In yet another aspect of the invention, an impact resistant film comprises a first outer layer comprising a blend of a high melt flow ethylene propylene copolymer and an elastomer; a second outer layer comprising a copolyester; a central layer comprising a polyolefin; an interior layer disposed between each of the two outer layers and the central layer respectively and comprising ethylene vinyl acetate copolymer having a melt index greater than about 1; and a polymeric adhesive layer disposed between and adhering the copolyester layer to an interior layer.

One additional example of an impact resistant film comprises a first outer layer comprising a blend of a high melt flow ethylene propylene copolymer and an elastomer; a second outer layer comprising a copolyester; a central layer comprising ethylene vinyl acetate copolymer, ethylene methyl acrylate copolymer, or a blend

thereof; an interior layer disposed between the first outer layer and the central layer and comprising a fractional melt index ethylene vinyl acetate copolymer; and a polymeric adhesive layer disposed between and adhering the copolyester layer to the central layer.

The present invention also includes a method of making an impact resistant film comprising providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; and extruding a first melt stream of the blend, a second melt stream of ethylene vinyl acetate copolymer, ethylene methyl acrylate copolymer, or a blend of ethylene vinyl acetate copolymer and ethylene methyl acrylate copolymer, and a third melt stream of high melt flow ethylene propylene copolymer optionally blended with the elastomer, to form a film.

An alternative method of making an impact resistant film comprises providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; and extruding a first melt stream of the blend, a second melt stream of a polymeric adhesive, and a third melt stream of a copolyester, to form a film.

Another aspect of the method comprises providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; extruding a first melt stream of the blend, a second melt stream of ethylene vinyl acetate copolymer, ethylene methyl acrylate copolymer, or a blend of ethylene vinyl acetate copolymer and ethylene methyl acrylate copolymer, a third melt stream of a polymeric adhesive, and a fourth melt stream of a copolyester, to form a film.

In still another aspect of the invention, a method of making an impact resistant film comprises providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; and extruding a first melt stream of the blend, a second melt stream of a polyolefin, a third melt stream of a copolyester, and a melt stream of a polymeric adhesive disposed between each of the first and second melt streams, and the second and third melt streams respectively, to form a film.

In yet another aspect of the invention, a method of making an impact resistant film comprises providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; and extruding the blend as a first melt stream, a second melt stream of ethylene vinyl acetate copolymer having a melt index greater than about 1, a central melt stream of a fractional melt index ethylene vinyl acetate copolymer, a fourth melt stream of ethylene vinyl acetate copolymer having a melt index greater than about 1, and a fifth melt stream of high melt flow ethylene propylene copolymer optionally blended with the elastomer, to form a film.

In still another aspect of the invention, a method of making an impact resistant film comprises providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; and extruding a first melt stream of the blend, a second melt stream of a fractional melt index ethylene vinyl acetate copolymer, a central melt stream of ethylene vinyl acetate copolymer having a melt index greater than about 1, a fourth melt stream of a fractional melt index ethylene vinyl acetate copolymer, and a fifth melt stream of high melt flow ethylene propylene copolymer optionally blended with the elastomer, to form a film.

In another aspect of the invention, a method of making an impact resistant film comprises providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; and extruding a first melt stream of the blend, a second melt stream of ethylene vinyl acetate copolymer having a melt index greater than about 1, a central melt stream of a polyolefin, a fourth melt stream of a polymeric adhesive, and a fifth melt stream of a copolyester, to form a film.

In still another aspect of the invention, a method of making an impact resistant film comprises providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; and extruding a first melt stream of the blend, a second melt stream of ethylene vinyl acetate copolymer having a melt index greater than about 1, a third melt stream of a polyolefin, a fourth melt stream of ethylene vinyl acetate copolymer having a melt index greater than about 1, and a fifth melt stream of a polymeric adhesive, and a sixth melt stream of a copolyester, to form a film.

An additional embodiment of a method of making an impact resistant film comprises providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; and extruding a first melt stream of the blend; a second melt stream of a fractional melt index ethylene vinyl acetate copolymer; a third melt stream of ethylene vinyl acetate copolymer, ethylene methyl acrylate copolymer, or a blend of ethylene vinyl acetate copolymer and ethylene methyl acrylate copolymer; a fourth melt stream of a polymeric adhesive; and a fifth melt stream of a copolyester, to form a film. Medical pouches may be made from a film of the present invention. Accordingly the invention also provides a medical pouch comprising a film of the invention.

FIG. 1 is a schematic cross-section of a film made in accordance with the invention;

FIG. 2 is a schematic cross-section of another film made in accordance with the invention;

FIG. 3 is a schematic cross-section of yet another film made in accordance with the present invention;

FIG. 4 is a schematic cross-section of still another film made in accordance with the present invention;

FIG. 5 is a schematic cross-section of another film made in accordance with the present invention;

FIG. 5a is a schematic cross-section of an alternative film made in accordance with the present invention;

FIG. 5b is a schematic cross-section of another alternative film made in accordance with the present inven-

tion; and

FIG. 6 is a schematic cross-section of yet another film made in accordance with the present invention.

Figure 1 shows a three layer impact resistant film 1 in accordance with the present invention. Sealant layer 10 comprises a blend of a high melt flow ethylene propylene copolymer (EPC) and an elastomer such as a styrene ethylene butylene styrene copolymer (SEBS). A suitable EPC resin is Z 9550 from Fina, or PLTD 685 from Exxon. The Fina material has an ethylene content of about 6.0%. Both EPC resins have a melt flow of about 10 grams/10 minutes (ASTM D 1238, Condition L). Other high melt flow ethylene propylene copolymers, and polypropylenes (PP) may be used. The elastomer is preferably a styrene ethylene butylene styrene copolymer (SEBS). The SEBS is preferably Kraton G 1652. This particular material may be regarded as a thermoplastic rubber, and also as a block copolymer with polystyrene end blocks and a rubbery polyethylene butylene midblock. A preferred blend range for sealant layer 10 includes between about 70% and 95% high melt flow EPC and between about 5% and 30% of an elastomer.

Other suitable elastomers for sealant layer 10 include styrene butadiene styrene copolymer, styrene isoprene styrene copolymer, and ethylene propylene rubber.

Although outer layer 14 may be identical to sealant layer 10 in terms of composition and thickness, these layers may differ depending on the particular end use. For example, the inner sealant layer 10 may have 20% elastomer to enhance impact resistance, while outer layer 14 may have only 10% elastomer. Elastomers such as SEBS adversely affect optics to some extent. Having a higher % elastomer in the sealant layer instead of the outer layer masks to some extent the loss in optical quality.

Outer layer 14 can also comprise a high melt flow EPC without any blended elastomer.

As an alternative, sealant layer 10 can comprise a high melt flow EPC without any blended elastomer, and outer layer 14 can comprise a blend of high melt flow EPC and an elastomer. Thus, elastomer can be present as a blend material in one or both outer layers of the present film.

The blend in outer layers 10 and/or 14 is preferably between 70% and 95% high melt flow ethylene propylene copolymer, and 5% to 30% by weight of elastomers such as styrene ethylene butylene styrene copolymer.

Interior layer 12, disposed between the two outer layers 10 and 14, comprises ethylene vinyl acetate copolymer (EVA), ethylene methyl acrylate copolymer (EMA), or blends of EVA and EMA. Preferably, the EVA has a vinyl acetate content of between about 18% and 35% by weight of the EVA. Even more preferably, the EVA has a vinyl acetate content of about 28% by weight of the EVA. Several commercially available EVA resins are suitable for intermediate layer 12. These include Elvax 3175 having a melt index of 6 and a 28% vinyl acetate content by weight of the EVA. Also useful is Elvax 3182, a 3 melt index resin with a vinyl acetate content of about 28% by weight of the EVA. Both of these resins are available from du Pont. Additionally, Exxon 767.36 (2.5 melt index, 30% vinyl acetate) and Exxon 760.36 (3 melt index, 27.5% vinyl acetate) are also suitable for intermediate layer 12. The intermediate layer 12 comprises preferably between 60 and 90% and more preferably about 80% of the total film thickness exclusive of sacrificial layers to be described hereafter.

Coextruding prior film structures, with differences in viscosity of the respective resins can make coextrusion difficult to perform satisfactorily. For example, severe melt ripples can sometimes result. In these situations, an additional outer layer of for example low density polyethylene is adhered to each of the outer layers. These additional layers function as sacrificial layers which are stripped away after the coextruded film has been produced. This allows the blend layers to function as sealant layers if necessary.

The present invention eliminates the need for sacrificial layers by providing a high melt flow EPC which more closely matches the viscosity of for example relatively thick internal EVA layers.

In an alternative embodiment for Figure 1, between about 70% and 95% of a high melt flow EPC is blended with between about 5 and 30% of an elastomer such as SEBS. This blend is coextruded with a flexible copolyester such as the Ecdel 9967 material described below, along with a polymeric adhesive (such as those described below) which is disposed between and serves to bond the blend layer to the flexible copolyester layer. In this alternative embodiment, the central polymeric adhesive layer is preferably a thin layer (relative to the two outer layers), compared with the relatively thick central layer 12 as depicted in Figure 1.

Figure 2 shows a four layer film made in accordance with the present invention. Outer layer 26 is preferably a blend of high melt flow EPC and the elastomer material described for outer layers 10 and 14 of the three layer structure.

Interior layer 24 comprises an EVA, EMA, or blends of EVA and EMA such as those described earlier. The second outer layer 20 is a flexible copolyester.

Adhesive layer 22 is a polymeric adhesive such as a modified ethylene methyl acrylate copolymer or modified ethylene vinyl acetate copolymer. Certain ethylene unsaturated ester copolymers, unmodified, may also be suitable for layer 22 in order to bond the interior EVA layer 24 to outer copolyester layer 20.

In addition, other polymeric adhesive materials may be suitable for layer 22 as well as the adhesive layers

of other embodiments of the present invention. The choice of these adhesive materials depends on the selection of resins for the remaining layers of the film structure, in particular the resin layers which will be bonded by the adhesive layer. These additional adhesives are preferably chemically modified adhesives, often with acid or acid anhydride functionalities, and include chemically modified versions of the following: linear low density polyethylene, very low density polyethylene, high density polyethylene and polypropylene.

Suitable chemically modified adhesives include Bynel E 361 available from du pont, and Plexar 3382 available from Quantum/USI. The Bynel E 361 material is an EVA based polymeric adhesive with maleic anhydride graft copolymer. The plexar 3382 material is a EMA based chemically modified polymeric adhesive with maleic anhydride graft copolymer.

Also suitable for layer 22 is modified styrene ethylene butylene styrene copolymer available from Shell Chemical Company as Kraton FG 1901X rubber.

Figure 3 shows a five layer film 3 substantially like the four layer film described earlier, but with an additional layer 36 of a polymeric adhesive such as a modified ethylene methyl acrylate copolymer or a modified ethylene vinyl acetate copolymer. Layer 36 can also comprise one or more of the adhesives described above for Fig. 2. Layer 36 can also comprise a blend of ethylene propylene copolymer and very low density polyethylene. A preferred blend is 50% EPC and 50% VLDPE. Thus, layer 38 of Figure 3 corresponds to layer 26 of Figure 2, layer 34 of Figure 3 corresponds to layer 24 of Figure 2, layer 32 of Figure 3 corresponds to layer 22 of Figure 2, and layer 30 of Figure 3 corresponds to layer 20 of Figure 2.

The outer layers 30 of Figure 3 and 20 of Figure 2 are a flexible copolyester.

More preferably, a copolymer of polyether and polyethylene terephthalate, such as Eastman Ecdel 9965 from Eastman Chemical Products, Inc. is used for outer layers 30 and 20. Other suitable flexible copolyesters are Ecdel 9966 and Ecdel 9967 all available from Eastman. These particular copolyesters are characterized by inherent viscosities ranging from 1.05 to 1.28, and by the use of 1,4 cyclohexane dimethanol, 1,4 cyclohexane dicarboxylic acid, and polytetramethylene glycol ether as reactants in producing the flexible copolyester resins.

Various polymeric materials or blends of materials may be used for adhesive layers 32, 36 and 22 provided that the material used imparts sufficient adhesion between outer layers and the central or interior polyolefin layer. When a flexible copolyester is used for outer layer 30, the preferred material for layer 32 is a chemically modified ethylene methyl acrylate copolymer with a carboxylic acid or acid anhydride functionality. An especially preferred commercial resin is plexar 3382 available from Quantum.

Other suitable commercial resins are Bynel E162 and Bynel E361, both chemically modified EVA materials available from du Pont.

The central layer 34 of Fig. 3 comprises a polyolefin and more preferably an EVA such as those described earlier, or a very low density polyethylene (VLDPE) such as DEFD 1362 available from Union Carbide.

Figure 4 shows an alternative embodiment being a five layer film 4. In applications where improved melt strength is required, the film described for Figure 1 can be further improved by introducing a fractional melt index EVA into the center of the structure so that layer 46 of Figure 4 is a fractional melt index (i.e. less than 1.0 melt index) EVA, and layers 48 and 44 disposed on either side of the layer 46, comprise the high vinyl acetate, high (greater than 1.0) melt index EVA described earlier for central layer 12. The total EVA content of this alternative embodiment is still preferably between 80% and 90%, and more preferably about 80% of the total film thickness. Examples of a fractional melt index EVA are Elvax 3135 and 3165, both available from du Pont.

In one variation of this alternative embodiment, the central layers 44, 46, and 48 may be reversed. In this variation, the fractional melt index EVA would form layers 44 and 48, and the central layer 46 would comprise the high vinyl acetate EVA.

Layers 42 and 50 of Figure 4 correspond to layers 14 and 10 respectively of Figure 1.

In Figure 5, a six layer film structure 5 is shown.

In this embodiment, a central layer 48 comprises a polyolefin, and preferably a fractional melt index EVA, high density polyethylene (HDPE), VLDPE, a blend of VLDPE and EVA, a blend of polypropylene (or EPC) and EVA, a blend of polypropylene (or EPC) and EMA, or a triple blend of polypropylene (or EPC) and EMA and EVA.

Intermediate layers 44 and 48 comprise an ethylene vinyl acetate copolymer having a melt index greater than about 1.0.

Outer layer 26 is a blend of high melt flow EPC and elastomer as described earlier for Figs. 1 and 2.

Outer layer 20 is a copolyester as described above for Fig. 2.

Layer 22 comprises a polymeric adhesive as described above for Fig. 2.

In an alternative arrangement for the film of Figure 5, the relative position of layers 46 and 44 is reversed (see Figure 5a). In the preferred embodiment, this puts identical or substantially identical layers 48 and 44 next to each other in the multilayer film structure. Even when produced from two discrete melt streams, layers 48

and 44 can become in effect one thickened layer 60 (see Figure 5b). The inventor has found that bringing the EVA material of layer 44 closer to sealant layer 26 improves the radio frequency (RF) sealability of containers made from the inventive film.

In Figure 6, a five layer film structure 6 is shown. This structure is essentially like the structure shown in Figure 2, but with a layer 54 of a fractional melt index EVA (e.g. Elvax 3135 or Elvax 3165) added to the structure. The films as described are preferably manufactured by a cast coextrusion process.

### EXAMPLES

Exemplary multi-layer structures of Examples 1 through 3 were cast coextruded and irradiated. These structures are viewed as potential replacements for polyvinyl chloride bags. Examples 1 through 11, in part reflected in the detailed description of the preferred embodiments hereinbefore described, are discussed below with their respective formulations. The list for each example begins with the inside or sealant layer, and ending with the outside layer. Unless otherwise denoted, the Examples include the following materials:

EPC <sub>1</sub> =	NO 54
SEBS <sub>1</sub> =	Kraton G 1652
flexible copolyester <sub>1</sub> =	Ecdel 9965;
flexible copolyester <sub>2</sub> =	Ecdel 9967
EVA <sub>1</sub> =	Elvax 3182-2
VLDPE <sub>1</sub> =	DEFD 1362
Adhesive <sub>1</sub> =	Bynel E 381
Adhesive <sub>2</sub> =	Plexar 3382

In Example 1, the multi-layer film comprised 80% EPC<sub>1</sub> + 20% SEBS<sub>1</sub>/EVA<sub>1</sub>/Adhesive<sub>1</sub>/Flexible Copolyester<sub>1</sub>. The outer layer of flexible copolyester included about 5% by weight of the outer layer of a masterbatch including Irganox 1010, a high molecular weight stabilizer. This masterbatch was included in like amount in the flexible copolyester layer of Examples 2 and 3.

In Example 2, the multi-layer film comprised the same construction as the films of Example 1, but with a blend layer comprising 90% EPC<sub>1</sub> + 10% SEBS<sub>1</sub>.

In Example 3 a multi-layer film comprised 80% EPC<sub>1</sub> + 20% SEBS<sub>1</sub>/50%VLDPE<sub>1</sub>+50%EPC<sub>1</sub>/VLDPE<sub>1</sub>/Adhesive<sub>2</sub>/flexible copolyester<sub>1</sub>.

Examples 4 through 6 are made by the same process described above for Examples 1 through 3, and comprise the same construction as Examples 1 through 3 respectively, except that the EPC of Examples 4 through 6 has a melt flow of about 5 grams/10 minutes (ASTM D 1238, Condition L).

Examples 7 through 9 are made by the same process described above for Examples 1 through 3, and comprise the same construction as Examples 1 through 3 respectively, except that the EPC of Examples 7 through 9 has a melt flow of about 10 grams/10 minutes (ASTM D 1238, Condition L).

Example 10 is made by the same process described above for Examples 1 through 3, and comprises 80% EPC<sub>1</sub> + 20% SEBS<sub>1</sub>/EVA<sub>1</sub>/50%EVA<sub>1</sub>+50%EPC<sub>1</sub>/EVA<sub>1</sub>/Adhesive<sub>1</sub>/flexible copolyester<sub>1</sub>.

Example 11 is made by the same process described above for Examples 1 through 3, and comprises 80% EPC<sub>1</sub> + 20% SEBS<sub>1</sub>/EVA<sub>1</sub>/EVA<sub>1</sub>/50%EVA<sub>1</sub>+50%EPC<sub>1</sub>/Adhesive<sub>1</sub>/flexible copolyester<sub>1</sub>.

EPC resins with intermediate melt flow rates of e.g. 7, 8, 12, and 13 grams/10 minutes (ASTM D 1238, Condition L) can also be used in the present invention.

Films in accordance with the present invention are preferably cross-linked. This is preferably done by irradiation, i.e. bombarding the film with particulate and non-particulate radiations such as high energy electrons from an accelerator or cobalt-60 gamma rays, to cross-link the materials of the film. Cross-linking increases the structural strength of film and/or the force at which the material can be stretched before tearing apart, and may also improve the optical properties of the film and change the high temperature properties of the film. A preferred irradiation dosage level is in the range of from about 2 Megarads (M.R.) to about 8 M.R.

Cross-linking may also be accomplished chemically e.g. by the use of peroxides.

Pouches made in accordance with the present invention may be sealed by various means well known in the art, including radiation frequency (R.F.) sealing, impulse and hot bar sealing.

The films according to the present invention are preferably formed by cast coextrusion as a tubular film. Containers for medical applications, or other desired end uses can be made directly from the coextruded, tubular film, or alternatively from rollstock material obtained from the tube after it has been slit and ply separated. A hot blown process can also be used to make the film, although optical properties of the resulting pouch would be inferior to those from a cast coextrusion process. Other processes, such as extrusion coating, conventional lamination, slot die extrusion, etc. can also be used to make the film of the present invention, although these alternative processes can be more difficult or less efficient than the preferred method.

It should be noted that the detailed description and specific examples which indicate the presently preferred embodiments of the invention are given by way of illustration only. Various changes and modifications within the spirit and scope of the claims will become apparent to those of ordinary skill in the art upon review of the above detailed description and examples.

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## Claims

1. An impact resistant film comprising:
  - two outer layers each comprising a high melt flow ethylene propylene copolymer; and
  - an interior layer disposed between the two outer layers and comprising an ethylene vinyl acetate copolymer, ethylene methyl acrylate copolymer or a blend thereof; at least one of the outer layers further comprising an elastomer.
2. A film according to claim 1 in which the interior layer comprises:
  - a central layer comprising a fractional melt index ethylene vinyl acetate copolymer and
  - an intermediate layer disposed between each of the two outer layers and the central layer respectively and comprising ethylene vinyl acetate copolymer having a melt index greater than about 1.
3. A film according to claim 1 in which the interior layer comprises:
  - a central layer comprising ethylene vinyl acetate copolymer having a melt index greater than about 1; and
  - an intermediate layer disposed between each of the two outer layers and the central layer respectively and comprising a fractional melt index ethylene vinyl acetate copolymer.
4. An impact resistant film comprising:
  - a) a first outer layer comprising a blend of a high melt flow ethylene propylene copolymer and an elastomer;
  - b) a second outer layer comprising a copolyester;
  - c) an interior layer comprising a polyolefin; and
  - d) a polymeric adhesive layer disposed between and adhering the second outer layer to the central layer.
5. A film according to claim 4 further comprising a second adhesive layer between and adhering the first outer layer to the interior layer.
6. A film according to claim 4 or 5 wherein the polyolefin is
  - a) ethylene vinyl acetate copolymer;
  - b) ethylene methyl acrylate copolymer;
  - c) a blend of ethylene vinyl acetate copolymer and ethylene methyl acrylate copolymer; or
  - d) very low density polyethylene.
7. A film according to claim 4, 5 or 6 in which the interior layer comprises:
  - a central layer comprising a polyolefin; and
  - an intermediate layer disposed between the first outer layer and the central layer, and comprising ethylene vinyl acetate copolymer having a melt index greater than about 1.
8. A film according claim 7 in which the interior layer comprises:
  - a central layer comprising a polyolefin and
  - an intermediate layer disposed between each of the two outer layers and the central layer respectively and comprising ethylene vinyl acetate copolymer having a melt index greater than about 1.
9. A film according to claim 7 or 8 wherein the central layer comprises a polyolefin which is:
  - a fractional melt index ethylene vinyl acetate copolymer;
  - high density polyethylene;
  - very low density polyethylene;
  - a blend of very low density polyethylene and ethylene vinyl acetate copolymer;
  - a blend of polypropylene or ethylene propylene copolymer and ethylene vinyl acetate copolymer;



a blend of polypropylene or ethylene propylene copolymer and ethylene methyl acrylate copolymer, or a blend of polypropylene or ethylene propylene copolymer and ethylene vinyl acetate copolymer and ethylene methyl acrylate copolymer.

- 5 10. A film according to claim 4, 5 or 6 in which the interior layer comprises:
  - a central layer comprising ethylene vinyl acetate copolymer, ethylene methyl acrylate copolymer, or a blend thereof; and
  - an intermediate layer disposed between the first outer layer and the central layer and comprising a fractional melt index ethylene vinyl acetate copolymer.
- 10 11. An impact resistant film comprising:
  - a first outer layer comprising a blend of a high melt flow ethylene propylene copolymer and an elastomer;
  - a second outer layer comprising a copolyester; and
  - 15 a polymeric adhesive layer disposed between and adhering the first and second outer layers.
12. A film according to any one of claims 4 to 11 wherein the polymeric adhesive comprises a chemically modified ethylene unsaturated ester copolymer.
- 20 13. A film according to claim 12 wherein the chemically modified ethylene unsaturated ester copolymer is an adhesive which is chemically modified ethylene methyl acrylate copolymer or chemically modified ethylene vinyl acetate copolymer.
- 25 14. A film according to any one of claims 4 to 11 wherein the polymeric adhesive comprises a chemically modified polymeric adhesive which is
  - modified linear low density polyethylene;
  - modified very low density polyethylene;
  - modified high density polyethylene;
  - modified polypropylene or
  - 30 modified styrene ethylene butylene styrene copolymer.
15. A film according to any one of the preceding claims wherein the elastomer is:
  - styrene ethylene butylene styrene copolymer;
  - styrene butadiene styrene copolymer;
  - 35 styrene isoprene styrene copolymer; or
  - ethylene propylene rubber.
16. A film according any one of the preceding claims wherein at least one outer layer comprises a blend of 70% to 95% high melt flow ethylene propylene copolymer, and 5% to 30% of a elastomer by weight.
- 40 17. A film according to any one of the preceding claims wherein the interior layer comprises ethylene vinyl acetate copolymer having a vinyl acetate content from 188 to 358 by weight of the ethylene vinyl acetate copolymer.
- 45 18. A film according to claim 17 wherein the ethylene vinyl acetate copolymer has a melt index greater than about 1.
19. A method of making a film as claimed in any one of the preceding claims comprising:
  - providing a blend of a high melt flow ethylene propylene copolymer and an elastomer; and extruding
  - 50 i) a first melt stream of the blend of ethylene propylene copolymer and elastomer
  - ii) a second melt stream of ethylene vinyl acetate copolymer, ethylene methyl acrylate copolymer, or a blend of ethylene vinyl acetate copolymer and ethylene methyl acrylate copolymer, and
  - iii) a third melt stream of high melt flow ethylene propylene copolymer optionally blended with elastomer, to form a film; or
  - 55 extruding
  - i) a first melt stream of the blend of ethylene propylene copolymer and elastomer,
  - ii) a second melt stream of a polyolefin,
  - iii) a third melt stream of a copolyester, and

iv) a melt stream of a polymeric adhesive disposed between the second and third melt streams respectively, to form a film; or  
extruding

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i) a first melt stream of the blend of ethylene propylene copolymer and elastomer,  
ii) a second melt stream of a polymeric adhesive, and  
iii) a third melt stream of a copolyester, to form a film.

10 20. A medical pouch comprising a film as claimed in any one of claims 1 to 18.

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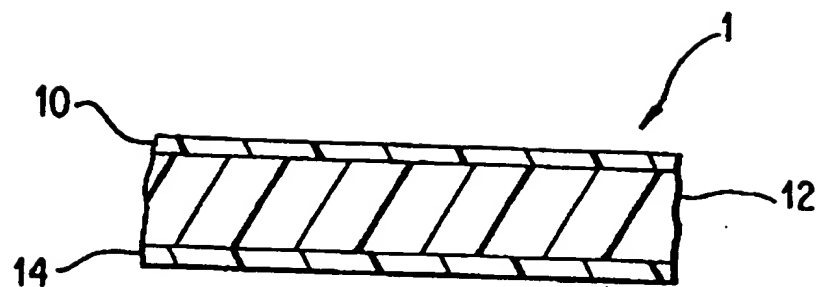


FIG. 1

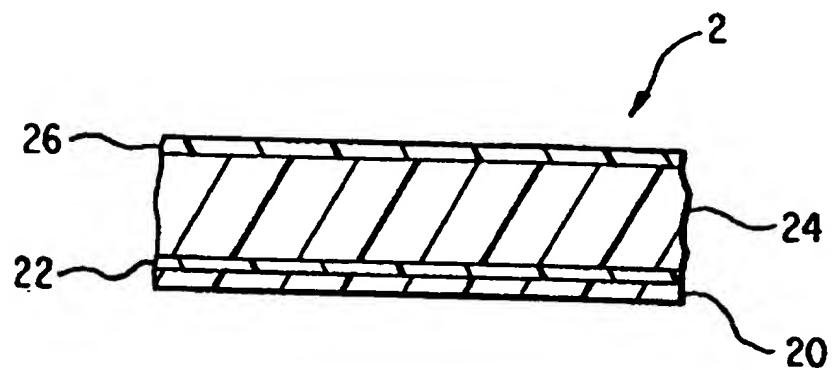


FIG. 2

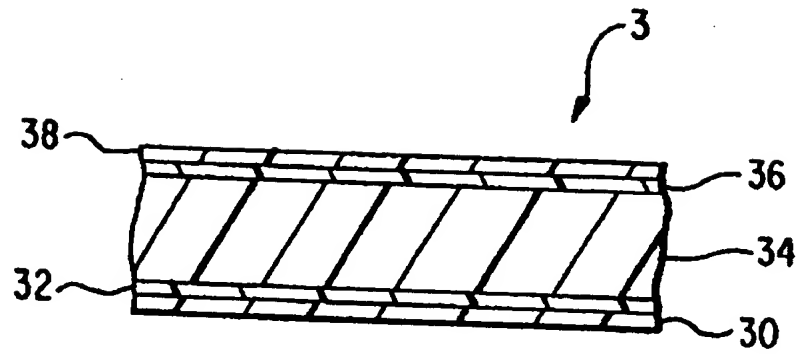


FIG. 3

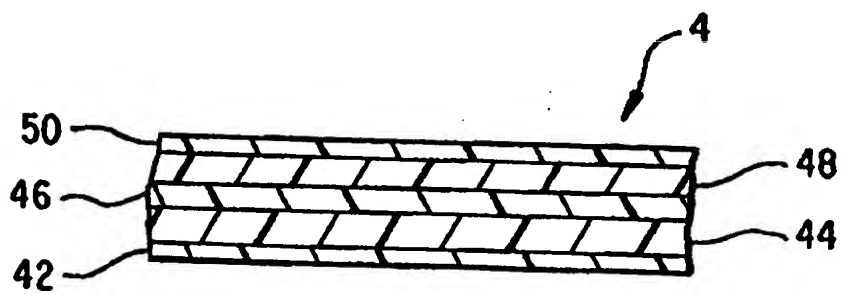


FIG. 4

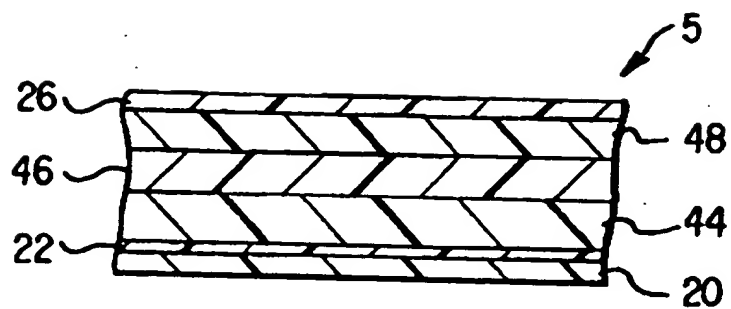


FIG. 5

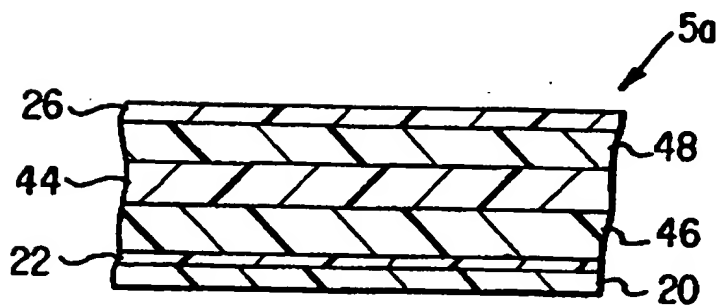


FIG. 5a

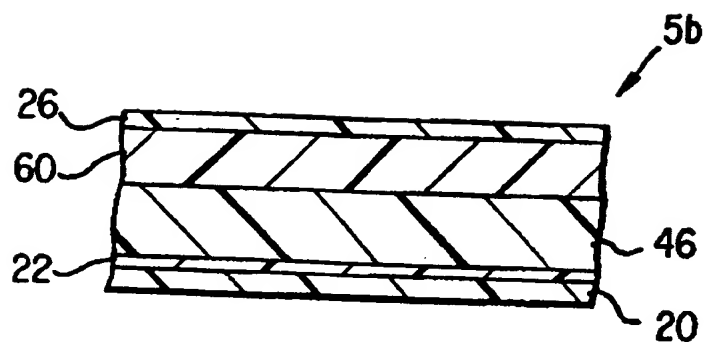


FIG. 5b

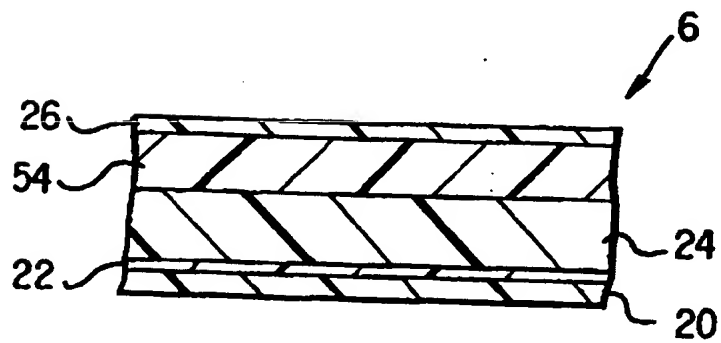


FIG. 6



European Patent  
Office

# EUROPEAN SEARCH REPORT

Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 91306746.8
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. CL.5)
X	US - A - 4 599 276 (MARTINI) * Claims *	1-3, 15-20	B 32 B 27/30 B 32 B 27/32 B 32 B 27/36 A 61 J 1/00
A		4-11	
D,X	US - A - 4 643 926 (MUELLER) * Claims *	4-20	
A		1-3	
			TECHNICAL FIELDS SEARCHED (Int. CL.5)
			B 32 B A 61 J
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 24-10-1991	Examiner WEIGERSTORFER
<p><b>CATEGORY OF CITED DOCUMENTS</b></p> <p>X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure F: intermediate document</p> <p>T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons A: member of the same patent family, corresponding document</p>			

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